

09/17/169

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 29 December 2000 (29.12.00)	To: Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/IE00/00060	Applicant's or agent's file reference P00-36-PCT
International filing date (day/month/year) 10 May 2000 (10.05.00)	Priority date (day/month/year) 20 May 1999 (20.05.99)
Applicant JEARY, Theresa, Ann et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

28 November 2000 (28.11.00)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

Date of mailing (day/month/year)
09 January 2001 (09.01.01)

From the INTERNATIONAL BUREAU

To:

ANNE RYAN & CO.
60 Northumberland Road
Ballsbridge
Dublin 4
IRLANDE

Date of mailing (day/month/year) 09 January 2001 (09.01.01)	
Applicant's or agent's file reference P00-36-PCT	IMPORTANT NOTIFICATION
International application No. PCT/IE00/00060	International filing date (day/month/year) 10 May 2000 (10.05.00)

1. The following indications appeared on record concerning:

the applicant the inventor the agent the common representative

Name and Address STARK, Paul 37 Auburn Heights Athlone County Westmeath Ireland	State of Nationality IE	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

the person the name the address the nationality the residence

Name and Address STARK, Paul 37 Auburn Heights Athlone County Westmeath Ireland	State of Nationality GB	State of Residence IE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:
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<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Eugénia Santos Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

TECH CENTER
REC'D 05 SEP 2001
NOV 09 2001
WIPO PCT
600/2900

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECEIVED

Applicant's or agent's file reference P00-36-PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IE00/00060	International filing date (day/month/year) 10/05/2000	Priority date (day/month/year) 20/05/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/50			
Applicant ELAN CORPORATION, PLC et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
 2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 28/11/2000	Date of completion of this report 03.09.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lindner, A Telephone No. +49 89 2399 8640



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IE00/00060

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-56 as originally filed

Claims, No.:

1-19 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IE00/00060

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.

claims Nos. 11, 18, 19.

because:

the said international application, or the said claims Nos. 19 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11, 18 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the standard.

the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IE00/00060

No: Claims 1-10, 12-17, 19

Inventive step (IS) Yes: Claims
No: Claims

Industrial applicability (IA) Yes: Claims 1-18
No: Claims

2. Citations and explanations
see separate sheet

Re Item III

**Non-establishment of opinion with regard to novelty, inventive step and
industrial applicability**

1. The subject-matter of claims 11 and 18 does not meet the requirements of article 6 PCT, because the term 'substantially as hereinbefore described and exemplified' is not clear.
2. Claim 19 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

3. Reference is made to the following documents:

D1 = WO 99/01122

D2 = WO 97/03670

D3 = EP-A-0 797 991

D4 = WO 99/01121

4. D1 describes multiparticulate dosage forms comprising sertraline coated with a polymer impermeable to the active agent. Mixtures of Eudragit^R-L and Eudragit^R-R are the preferred coatings according to D1 (D1: claims 14-17: p. 13, l. 17-21). As a consequence, D1 destroys the novelty of independent claim 1 (article 33(2) PCT). In this context, it is noted that the release period is considered to be implicitly disclosed in D1 in view of the fact that the same coating material is used (Eudragit^R-L and Eudragit^R-R).
5. Example 5 of D2 discloses a tablet comprising a core containing paroxetine HCl as active agent and a coating comprised of Eudragit^R RS 100. As a consequence, D2 destroys the novelty of independent claim 1 (article 33(2) PCT). In this context

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IE00/00060

it is noted that tablets are considered multiparticulate systems. As for the implicit disclosure of the release rate, cf. paragraph 4 above.

6. D3 refers to 24 hour extended release dosage formulations in the form of capsules containing venlafaxine as active agent and a film coating essentially consisting of ethylcellulose (D3: abstract; p. 2, l. 39 - p. 3, l. 39). D3 is also detrimental for the novelty of present claim 1 (article 33(2) PCT).
7. D4 discloses coated multiparticulates comprising sertraline as active agent having a release rate of up to 24h (D4: p.4, l. 5-21). Coated multiparticulates are also described in the examples of D4 (see e.g. example 8). As a consequence, D4 is detrimental for the novelty of present claim 1.
8. The antidepressive activity of SSRIs is generally known and also described in D1-D4 (see e.g. D4: p. 1, l. 11-12). The subject-matter of independent claim 19 is therefore not novel over D1-D4, either (article 33(2) PCT).
9. The dependent claims 2-10 and 12 to 17 do not contain additional technical features which might establish novelty and an inventive step over D1 to D4 (articles 33(2) and 33(3) PCT). These claims are only allowable in combination with patentable independent claims. In this context, it is noted that the release inhibiting activity of Eudragit^R, in particular of Eudragit^R RS and RL is common knowledge so that the release as claimed in the present application do not appear to be able to give rise to an inventive activity.

INTERNATIONAL SEARCH REPORT

Int'l Application No.
PCT/EP 00/00060

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/50 A61K31/137 A61P25/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 01122 A (PFIZER) 14 January 1999 (1999-01-14) claims 1-20, 27-53 examples 4,5	1-19
A	WO 99 01121 A (PFIZER) 14 January 1999 (1999-01-14) claims example 8	1-19
A	WO 97 03670 A (SMITHKLINE BEECHAM) 6 February 1997 (1997-02-06) claims examples 3-7	1-19
A	GB 2 325 623 A (ELI LILLY) 2 December 1998 (1998-12-02) claims	1-19
		-/-

COPY

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

3 August 2000

Date of mailing of the international search report

09/08/2000

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Scarpioni, U

INTERNATIONAL SEARCH REPORT

Int'l Application No.
PCT/00/00060

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 797 991 A (AMERICAN HOME PRODUCTS) 1 October 1997 (1997-10-01) claims	1-19

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00060

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9901122	A 14-01-1999	AU 7545198 A EP 1007024 A HR 980376 A NO 996519 A		25-01-1999 14-06-2000 30-04-1999 29-02-2000
WO 9901121	A 14-01-1999	AU 7544998 A EP 0999830 A HR 980379 A NO 996518 A		25-01-1999 17-05-2000 30-04-1999 29-02-2000
WO 9703670	A 06-02-1997	AU 6659196 A BG 102259 A BR 9609857 A CN 1195986 A CZ 9800183 A EP 0839039 A HU 9900299 A JP 11509539 T NO 980240 A PL 324553 A SK 5398 A		18-02-1997 30-09-1998 16-03-1999 14-10-1998 17-06-1998 06-05-1998 28-09-1999 24-08-1999 20-01-1998 08-06-1998 08-07-1998
GB 2325623	A 02-12-1998	US 5910319 A AU 6904898 A BE 1011925 A BR 9801989 A CA 2234826 A CN 1200924 A CZ 9801143 A DE 19823940 A FI 980846 A FR 2763846 A GR 98100188 A HU 9800882 A IT MI980908 A JP 10330253 A LT 98058 A,B LV 12176 A LV 12176 B NL 1009259 C NO 982197 A NZ 330192 A PL 326134 A PT 102152 A SE 9801336 A SI 9800128 A,B US 5985322 A		08-06-1999 03-12-1998 07-03-2000 08-02-2000 29-11-1998 09-12-1998 16-12-1998 03-12-1998 30-11-1998 04-12-1998 29-01-1999 28-03-2000 28-10-1999 15-12-1998 26-10-1998 20-12-1998 20-03-1999 01-12-1998 30-11-1998 30-08-1999 07-12-1998 31-12-1998 30-11-1998 28-02-1999 16-11-1999
EP 797991	A 01-10-1997	AU 1640097 A BR 9701304 A CA 2199778 A CN 1164389 A CZ 9700772 A HU 9700589 A JP 10007552 A NO 971206 A NZ 314442 A PL 318954 A		02-10-1997 29-09-1998 25-09-1997 12-11-1997 12-11-1997 29-09-1997 13-01-1998 26-09-1997 29-06-1999 29-09-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00060

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 797991 A		SK 30197 A ZA 9702403 A	08-10-1997 21-09-1998